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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DANIEL KRIPKE, on behalf of himself and the general public,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner, United States Food and Drug Administration; UNITED STATES CENTER FOR DRUG EVALUATION AND RESEARCH; JANET WOODCOCK, in her official capacity as Director, United States Center for Drug Evaluation and Research; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and SYLVIA MATTHEWS BURWELL, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

Case No: 3:16-cv-1214-H-BLM

PLAINTIFF'S NOTICE OF APPEAL

Judge: The Honorable Marilyn L. Huff
Location: Courtroom 15A

TO THE CLERK OF THE COURT, ALL PARTIES, AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT Plaintiff Daniel Kripke hereby appeals to the United States Court of Appeals for the Ninth Circuit from the judgment entered against him on February 3, 2017 ("Judgment") (Doc. 19), attached hereto as **Exhibit A**. This Judgment followed the Court's February 2, 2017 order granting Defendants' motion to dismiss (Doc. 18), attached hereto as **Exhibit B.**

The service list that should be used for the appeal is attached hereto as **Exhibit C.**

DATED: February 6, 2017

Respectfully Submitted,

/s/ Gregory S. Weston

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EXHIBIT A

United States District Court

SOUTHERN DISTRICT OF CALIFORNIA

Daniel Kripke, on behalf of himself and the general public

Plaintiff,

V.

United States Food and Drug Administration; SEE ATTACHMENT

Defendant.

Civil Action No. 16-cv-01214-H-BLM

JUDGMENT IN A CIVIL CASE

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS HEREBY ORDERED AND ADJUDGED:

The Court grants Defendants' motion to dismiss Plaintiff's first amended complaint for failure to state a claim. The Court dismisses Plaintiff's first amended complaint without leave to amend.

Date: 2/3/17

CLERK OF COURT
JOHN MORRILL, Clerk of Court
By: s/ A. Garcia
A. Garcia, Deputy

United States District Court

SOUTHERN DISTRICT OF CALIFORNIA

(ATTACHMENT)

Civil Action No. 16-cv-01214-H-BLM

Defendant
Robert M. Califf, in his official capacity as Commissioner, United States Food and Drug Administration

Defendant
United States Center for Drug Evaluation and Research

Defendant
Janet Woodcock, in her official capacity as Director, United States Center for Drug Evaluation and Research

Defendant
United States Department of Health and Human Services

Defendant
Sylvia Matthews Burwell, in her official capacity as Secretary, United States Department of Health and Human Services

Defendant
Ms. Monica Christine Groat, U.S. Department of Justice Consumer Protection Branch

EXHIBIT B

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DANIEL KRIPKE, on behalf of himself and the general public, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Case No.: 16-cv-1214-H-BLM **ORDER GRANTING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT** [Doc. No. 11.]

On October 31, 2016, Defendants filed a motion to dismiss Plaintiff's first amended complaint. (Doc. No. 11.) On November 21, 2016, Plaintiff filed an opposition to Defendants' motion. (Doc. No. 13.) On December 2, 2016, Defendants filed a reply. (Doc. No. 16.) The Court took the matter under submission. (Doc. No. 17.) For the reasons below, the Court grants Defendants' motion to dismiss and dismisses Plaintiff's first amended complaint without leave to amend.

Background

The following facts are taken from the allegations in Plaintiff's first amended complaint. Plaintiff Daniel Kripke is an Emeritus Professor at the University of California, San Diego Department of Psychiatry. (Doc. No. 8, FAC ¶ 26.) During his 40-year career,

Plaintiff has been active in treating insomnia patients and in teaching about the treatment of insomnia. (Id.) During his career, Plaintiff has conducted and published extensive research into the dangers associated with hypotonic drugs (sleeping pills). (Id.)

Plaintiff alleges that hypnotic drugs greatly increase all-cause mortality, produce an excess of death at nights, and cause (1) serious and lethal infections, (2) increased cancer risk, (3) clinical depression and suicide, and (4) an increase in the frequency and severity of injuries due to auto collusions, falls, and other accidents. (Id. ¶ 10.) Plaintiff alleges that despite this, the United States Food and Drug Administration has failed to appropriately regulate hypnotic drugs and to order the required epidemiologic health testing. (Id. ¶ 7.)

On October 26, 2015, Plaintiff submitted a citizen petition to the FDA requesting that the agency:

> (1) require that manufacturers of the Hypnotics[1] conduct comprehensive post-market randomized placebo-controlled trials quantifying risks and benefits to patients; (2) require that manufacturers of each of the Hypnotics promptly issue "Dear Doctor" letters regarding the known and suspected risks to patients of long-term use of the Hypnotics; (3) implement enhanced reporting of all prescription use of the Hypnotics; (4) restrict off-label prescription of the Hypnotics; (5) require labeling of mortality hazards on the Hypnotics; (6) require enhanced informed consent for the Hypnotics; and (7) restrict indications for the Hypnotics pending the results of post-market studies . . . .

(Id. ¶ 13.) The petition was accepted as filed on October 27, 2015. (Id.)

On April 21, 2016, the FDA sent a letter to Plaintiff's counsel stating:

> I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition received on October 27, 2015 and submitted on behalf of Dr. Daniel Kripke. The petition requests that the Agency take eight specified "administrative actions" with respect to

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[1] The FAC defines "Hypnotics" as "zolpidem, temazepam, eszopiclone, zaleplon, triazolam, flurazepam, and quazepam, in all brands and forms prescribed to treat insomnia or patient-reported sleep disorders, and any barbiturates still prescribed including pentobarbital, amobarbital, and secobarbital, either on- or off-label to induce sleep." (Doc. No. 8, FAC ¶ 9.)

"at least" the following "hypnotic drugs":

> zolpidem, temazepam, eszopiclone, zaleplon, triazolam, flurazepam, and quazepam, in all brands and forms prescribed to treat insomnia or patient reported sleep disorders, and any barbiturates including pentobarbital, amobarbital, and secobarbital still prescribed, either on- or off-label, to induce sleep.
>
> FDA has been unable to reach a decision on the petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to the petition as soon as we have reached a decision on the request.

(Id. ¶ 15, Ex. 1.) Plaintiff alleges that this response is statutorily inadequate, and the FDA has unreasonably delayed ruling on his petition. (Id. ¶¶ 17-18.)

On May 19, 2016, Plaintiff filed a putative class action against Defendants United States Food and Drug Administration, Robert M. Califf, United States Center for Drug Evaluation and Research, Janet Woodcock, United States Department of Health and Human Services, and Sylvia Matthews Burwell, alleging claims for: (1) agency action unlawfully withheld; (2) agency action that is arbitrary or capricious action, abuse of discretion, or otherwise not in accordance with the law; and (3) agency action unreasonably delayed. (Doc. No. 1, Compl.) In the complaint, Plaintiff requests an order compelling the FDA to respond to his petition and to take the actions requested in that petition, and for the Court to set specific deadlines for these actions. (Id. ¶ 20.) On October 17, 2016, Defendants filed a motion to dismiss Plaintiff's complaint. (Doc. No. 6.)

In response to Defendants' motion to dismiss, Plaintiff filed a first amended complaint against the Defendants pursuant to Federal Rule of Civil Procedure 15(a)(1), adding additional allegations and asserting the same three causes of action. (Doc. No. 8, FAC.) In light of Plaintiff filing a first amended complaint, the Court denied Defendants' motion to dismiss the original complaint as moot. (Doc. No. 10.) By the present motion, Defendants move to dismiss Plaintiff's first amended complaint pursuant to Federal Rule

of Civil Procedure 12(b)(1) for lack of standing and pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. (Doc. No. 11-1.)

Discussion

I. Legal Standards

A. Legal Standards for a Rule 12(b)(1) Motion to Dismiss

A defendant may move to dismiss an action for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Fed. R. Civ. P. 12(b)(1). "Rule 12(b)(1) jurisdictional attacks can be either facial or factual." White v. Lee, 227 F.3d 1214, 1242 (9th Cir. 2000). "In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction." Safe Air for Everyone v. Meyer, 373 F.3d 1035, 1039 (9th Cir. 2004). The factual allegations of the complaint are presumed to be true, and the complaint is only dismissed if the plaintiff failed to allege an element necessary for subject matter jurisdiction. See Savage v. Glendale Union High Sch. Dist. No. 205, 343 F.3d 1036, 1039 n. 1 (9th Cir. 2003); Orsay v. U.S. Dep't of Justice, 289 F.3d 1125, 1127 (9th Cir. 2002).

"By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction." Safe Air for Everyone, 373 F.3d at 1039. "In resolving a factual attack on jurisdiction, the district court may review evidence beyond the complaint without converting the motion to dismiss into a motion for summary judgment." Id. "The court need not presume the truthfulness of the plaintiff's allegations." Id. "The party asserting federal subject matter jurisdiction bears the burden of proving its existence." Chandler v. State Farm Mutual Auto. Ins. Co., 598 F.3d 1115, 1122 (9th Cir. 2010).

B. Legal Standards for a Rule 12(b)(6) Motion to Dismiss

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the pleadings and allows a court to dismiss a complaint if the plaintiff has failed to state a claim upon which relief can be granted. See Conservation Force v. Salazar, 646 F.3d 1240, 1241 (9th Cir. 2011). Federal Rule of Civil Procedure 8(a)(2) requires that

a pleading stating a claim for relief containing "a short and plain statement of the claim showing that the pleader is entitled to relief." The function of this pleading requirement is to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint will survive a motion to dismiss if it contains "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (quoting Twombly, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" Id. (quoting Twombly, 550 U.S. at 557). Accordingly, dismissal for failure to state a claim is proper where the claim "lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." Mendiondo v. Centinela Hosp. Med. Ctr., 521 F.3d 1097, 1104 (9th Cir. 2008).

In reviewing a Rule 12(b)(6) motion to dismiss, a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the plaintiff. See Retail Prop. Trust v. United Bhd. of Carpenters & Joiners of Am., 768 F.3d 938, 945 (9th Cir. 2014). But a court need not accept "legal conclusions" as true. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Further, it is improper for a court to assume the plaintiff "can prove facts which it has not alleged or that the defendants have violated the . . . laws in ways that have not been alleged." Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983). In addition, a court may consider documents incorporated into the complaint by reference and items that are proper subjects of judicial notice. See Coto Settlement v. Eisenberg, 593 F.3d 1031, 1038 (9th Cir. 2010).

If the court dismisses a complaint for failure to state a claim, it must then determine whether to grant leave to amend. See Doe v. United States, 58 F.3d 494, 497 (9th Cir. 1995). "'A district court may deny a plaintiff leave to amend if it determines that

'allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency,' or if the plaintiff had several opportunities to amend its complaint and repeatedly failed to cure deficiencies." Telesaurus VPC, LLC v. Power, 623 F.3d 998, 1003 (9th Cir. 2010) (internal quotation marks and citations omitted).

II. Analysis

A. Plaintiff's Claims for Agency Action Unlawfully Withheld or Unreasonably Delayed

In the FAC, Plaintiff alleges causes of action for agency action unlawfully withheld and unreasonably delayed under 5 U.S.C. § 706(1). (Doc. No. 8, FAC ¶¶ 120-29, 132-35.) Defendants argue that these claims should be dismissed because the FDA has not unreasonably delayed taking action on Plaintiff's petition, and the FDA's tentative response to the petition complied with the relevant regulations. (Doc. No. 11-1 at 18-24.) In addition, Defendants argue the other statutes referred to with respect to these claims fail to set forth a discrete agency action that the FDA was required to take. (Id. at 24-25.)

i. Legal Standards for 5 U.S.C. § 706(1) Claims

"Section 706(1) of the APA grants federal courts the power to 'compel agency action unlawfully withheld or unreasonably delayed.'" Hells Canyon Pres. Council v. U.S. Forest Serv., 593 F.3d 923, 932 (9th Cir. 2010) (quoting 5 U.S.C. § 706(1)). "This provision serves important interests, but does not give [a court] license to 'compel agency action' whenever the agency is withholding or delaying an action [a court] think[s] it should take. Instead, [a court's] ability to 'compel agency action' is carefully circumscribed to situations where an agency has ignored a specific legislative command." Id.; see also In re California Power Exch. Corp., 245 F.3d 1110, 1124 (9th Cir. 2001) (explaining that a federal court's authority "to issue mandamus relief from agency inaction is narrow"). Therefore, "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a discrete agency action that it is required to take." Norton v. S. Utah Wilderness All., 542 U.S. 55, 64 (2004) (emphasis removed) ("[T]he only agency action that can be compelled under the APA is action legally required."). "'Absent such an assertion, a Section 706(1)

claim may be dismissed for lack of jurisdiction.'" San Luis Unit Food Producers v. United States, 709 F.3d 798, 804 (9th Cir. 2013).

Further, even where a plaintiff has identified a discrete action that the agency is required to take, the "plaintiff must then further demonstrate that the agency unreasonably delayed or unlawfully withheld processing its decision." Asmai v. Johnson, 182 F. Supp. 3d 1086, 1093 (E.D. Cal. 2016). "[In] determining whether an agency's delay in issuing a final order is so 'egregious' as to warrant mandamus," a court must balance the TRAC[2] factors. California Power Exch., 245 F.3d at 1124; see Brower v. Evans, 257 F.3d 1058, 1068 (9th Cir. 2001). These factors are as follows:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"[;] (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason [;] (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake [;] (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority[;] (5) the court should also take into account the nature and extent of the interests prejudiced by the delay[;] and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

Brower, 257 F.3d at 1068. Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances before the court. Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1100 (D.C. Cir. 2003).

ii. The FDA's Alleged Failure to Respond to Plaintiff's Petition

Plaintiff alleges that the FDA's tentative response to his petition failed to comply with the 180-day deadline set forth in 21 C.F.R. § 10.30(e)(2). (Doc. No. 8, FAC ¶ 127.) 21 C.F.R. § 10.30(e)(2) provides:

[T]he Commissioner shall furnish a response to each petitioner within 180

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[2] Telecommunications Research & Action v. FCC (TRAC), 750 F.2d 70, 80 (D.C. Cir. 1984).

> days of receipt of the petition. The response will either:
>
> (i) Approve the petition . . . ;
>
> (ii) Deny the petition;
>
> (iii) Dismiss the petition if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or
>
> (iv) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

Plaintiff submitted his citizen petition to the FDA on October 26, 2015, and it was accepted as filed on October 27, 2015. (Doc. No. 8, FAC ¶ 13.) Less than 180 days later,[3] on April 21, 2016, the FDA provided Plaintiff with a tentative response stating that the "FDA has been unable to reach a decision on the petition because it raises complex issues requiring review and analysis by Agency officials." (Id. ¶ 15, Ex. 1.)

Plaintiff contends this response is statutorily inadequate. (Id. ¶ 17.) Plaintiff is incorrect. Cf. Iqbal, 556 U.S. at 678 (explaining that a court need not accept "legal conclusions" as true). Because the FDA's response was provided within 180 days from its receipt of Plaintiff's petition, and it provided a tentative response indicating why the FDA has been unable to reach a final decision on the petition, the FDA's response complied with 21 C.F.R. § 10.30(e)(2). See, e.g., Hill Dermaceuticals, Inc. v. U.S. Food & Drug Admin., 524 F. Supp. 2d 5, 10 (D.D.C. 2007) (finding that the FDA's tentative response "that 'FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities'" was sufficient to comply with 21 C.F.R. § 10.30(e)(2).); Biovail Corp. v. U.S. Food & Drug Admin., 448 F. Supp. 2d 154, 162 (D.D.C. 2006) ("[T]he defendant's

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[3] 180 days from October 27, 2015 is April 24, 2016.

tentative response is consistent with the text of [21 C.F.R. § 10.30(e)(2)]. The defendant issued a tentative response within 180 days and explained the reason it could not reach a decision within that time frame."). Plaintiff argues that FDA's response is inadequate because it does specifically state that the FDA has begun working on the petition, and it is not specifically responsive to the issues raised in his petition. (Doc. No. 8, FAC ¶ 16; Doc. No. 13 at 18.) But 21 C.F.R. § 10.30(e)(2) "'does not indicate that the FDA's reasoning must be of a certain degree of detail' and this Court declines to impose such a requirement when none is present on the face of § 10.30(e)(2)(iii)." Hill Dermaceuticals, Inc., 524 F. Supp. 2d at 11 (quoting Biovail Corp., 448 F. Supp. 2d at 162). Accordingly, because the FDA's tentative response complied with 21 C.F.R. § 10.30(e)(2), that regulation does not support Plaintiff's claims for agency action unlawfully withheld and agency action unreasonably delayed.[4]

Plaintiff also alleges that the FDA has unreasonably delayed ruling on his petition. (Doc. No. 8, FAC ¶¶ 18, 128, 134.) Defendants argue that a review of the TRAC factors shows that the FDA has not unreasonably delayed taking action on the petition. (Doc. No. 11-1 at 18-.) The Court agrees with Defendants.

5 U.S.C. § 555(b) provides that "within a reasonable time, each agency shall proceed to conclude a matter presented to it." "Section 555(b) imposes a general but nondiscretionary duty upon an administrative agency to pass upon a matter presented to it

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[4] The Court does not find persuasive Plaintiff's reliance on Sandoz, Inc. v. Leavitt, 427 F. Supp. 2d 29, 34 (D.D.C. 2006). (Doc. No. 13 at 18.) In Sandoz, the defendant conceded that the FDA did not take any of the alternative actions required by the relevant statute within the 180-day deadline. See 427 F. Supp. 2d at 34-35. In contrast, here, the FDA provided a tentative response indicating why it has been unable to reach a decision on the petition within the 180-day deadline as permitted by 21 C.F.R. § 10.30(e)(2)(iv).

The Court notes that Plaintiff also relies on the D.C. Circuit's decision in Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094 (D.C. Cir. 2003). (Doc. No. 13 at 18.) But Plaintiff's reliance on Mashpee Wampanoag is perplexing because Mashpee Wampanoag does not contain a discussion of 21 C.F.R. § 10.30(e)(2), and in that case the D.C. Circuit ultimately reversed the district court's earlier finding of unreasonable delay. See 336 F.3d at 1102.

'within a reasonable time.'" Mashpee Wampanoag, 336 F.3d at 1099.

Plaintiff's petition requests that the FDA take eight different actions with respect to ten different drugs. (See Doc. No. 8, FAC ¶¶ 9, 13, Ex. 1.) Even taking the allegations in the FAC and true, and drawing all reasonable inferences in favor of Plaintiff, it is entirely unreasonable for Plaintiff to assert that the FDA has unreasonably delayed deciding such a complex petition when that petition has only been pending for 15 months and Plaintiff added additional material to the petition only five months ago.[5] See Ctr. for Sci. in the Pub. Interest v. United States Food & Drug Admin., 74 F. Supp. 3d 295, 301 (D.D.C. 2014) ("Whether the Administration has unreasonably delayed its response to a petition can only be measured by reference to the complexity of the task. The more complex the petition, the more time an agency may need to adequately respond."); In re Pesticide Action Network N. Am., 532 F. App'x 649, 651 (9th Cir. 2013) ("The time [the agency] has taken to consider the 2007 Petition is not unreasonable in light of the complexity of the issue."); see also California Power Exch., 245 F.3d at 1125 ("The cases in which courts have afforded relief [under section 706(1)] have involved delays of years, not months.")

This conclusion is supported by a review of the other TRAC factors. Congress has not provided a specific timeframe for deciding citizen petitions such as Plaintiff's. "While [21 C.F.R. § 10.30(e)(2)] give[s] 180 days for a tentative response, [it] say[s] nothing about how long FDA has to issue an ultimate response to a citizen petition. The only applicable standard against which to measure that action is the APA's requirement that FDA act 'within a reasonable time.'" Ctr. for Sci. in the Pub. Interest, 74 F. Supp. 3d at 301. 15 months is not a reasonable time given the complexity of Plaintiff's petition. "Courts, moreover, routinely defer to the judgment of agencies when assessing timelines that involve complex scientific and technical questions." Id.; see In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991) ("The agency is in a unique—and authoritative—position to

[5] Indeed, Plaintiff's delay claim was even more unreasonable at the time the present action was filed because, at that time, his petition has only been pending for seven months.

view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way."). Further, although courts require greater agency promptness with respect to actions involving human health and welfare, "this factor alone can hardly be considered dispositive when, as in this case, virtually the entire docket of the agency involves issues of this type." Sierra Club v. Thomas, 828 F.2d 783, 798 (D.C. Cir. 1987); see Pesticide Action Network, 532 F. App'x at 651; see also Ctr. for Sci. in the Pub. Interest, 74 F. Supp. 3d at 304 ("Because everything the [FDA] does involves health and welfare, [Defendant] contends, the fact that Plaintiffs' petition also implicates these concerns is far less significant than it might otherwise be. This is correct."). Finally, Plaintiff agrees that there are no allegations of impropriety by the FDA in this action. (Doc. No. 13 at 23.) Thus, a review of the TRAC factors establishes that the FDA has not unreasonably delayed ruling on Plaintiff's petition as a matter of law. [6]

Plaintiff argues that an agency must not only rule on a petition within a reasonable amount of time, but the agency must also begin to consider the petition within a reasonable amount of time. (Doc. No. 13 at 18-19.) But the only authority Plaintiff provides to the Court in support of this contention is the D.C. Circuit's decision in Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1099 (D.C. Cir. 2003). Nowhere in Mashpee Wampanoag does the D.C. Circuit ever specifically hold that section 706(1)'s unreasonable delay standard applies to the time when the agency begins to consider a petition. See 336 F.3d at 1099. Further, even if section 706(1)'s unreasonable delay standard applied to the time when the agency begins to consider a petition, Defendants have represented to the Court that the FDA has indeed begun evaluating of the petition. (Doc. No. 16 at 10.) In sum, Plaintiff has failed to adequately allege that the FDA has unreasonably delayed ruling

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[6] The Court does not find persuasive Plaintiff's reliance on a report from the Inspector General of the U.S. Department of Health and Human Services. (Doc. No. 13 at 16.) The report itself is 15 years old. Further, the report criticizes the FDA for taking several years, and in some cases decades, to fully answer some citizen petitions. (Doc. No. 12-1, Weston Decl. Ex. 2 at 1) But, here, the FDA has not delayed answering Plaintiff's petition for several years. The petition has only been pending for 15 months.

on his petition.

ii. The FDA's Alleged Failure to Take the Final Actions Requested in the Petition

Plaintiff also alleges that the FDA's failure to take the final actions requested in Plaintiff's petition constitutes agency action unlawfully withheld. (Doc. No. 8, FAC ¶ 129.) But this specific aspect of Plaintiff's claim is not cognizable through a claim under section 706(1). "The sole remedy available under § 706(1) is for the court to 'compel agency action,' such as by issuing an order requiring the agency to act, without directing the substantive content of the decision." Ctr. for Food Safety v. Hamburg, 954 F. Supp. 2d 965, 968 (N.D. Cal. 2013); accord Audubon Soc. of Portland v. Jewell, 104 F. Supp. 3d 1099, 1102 (D. Or. 2015); see also Norton, 542 U.S. at 65 ("[W]hen an agency is compelled by law to act within a certain time period, but the manner of its action is left to the agency's discretion, a court can compel the agency to act, but has no power to specify what the action must be."). Thus, the Court can at most issue an order compelling the FDA to respond to Plaintiff's petition. The Court cannot through a section 706(1) claim issue an order requiring the FDA to grant the petition and take the specific final actions requested in the petition. See id.

iii. The Other Statutes Cited By Plaintiff In Support of These Claims

In support of his claim for agency action unlawfully withheld, Plaintiff also identifies several additional food and drug statutes. (Doc. No. 8, FAC ¶¶ 121-24.) Defendants argue that these additional statutes fail to set forth discrete actions that the FDA was required to take. (Doc. No. 11-1 at 24-25.)

Plaintiff identifies the FDA's statutory mission that "includes the duty to 'protect the public health by ensuring that . . . human . . . drugs are safe and effective . . . .'" (Doc. No. 8, FAC ¶ 121 (quoting 21 U.S.C. § 393(b)(2)).) Plaintiff also notes that 21 U.S.C. § 393(b)(1) "requires the FDA to 'promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.'" (Id. ¶122 (quoting 21 U.S.C. § 393(b)(1)).) But these broad

statutory missions are insufficient to support a § 706(1) claim. "Statutory goals that are 'mandatory as to the object to be achieved' but leave the agency with 'discretion in deciding how to achieve' those goals are insufficient to support a 'failure to act' claim because such discretionary actions are not 'demanded by law.'" San Luis Unit Food Producers, 709 F.3d at 803; see also Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 760 F.3d 151, 178 (2d Cir. 2014) (Katzmann, C.J., dissenting) ("[21 U.S.C. § 393(b)'s] broad statutory mandate to 'promote the public health' and 'ensur[e] that human and veterinary drugs are safe and effective' does not compel the agency to use any particular method to attain those goals.").

In the FAC, Plaintiff also cites to 21 U.S.C. §§ 352(f), 352(j) 355-1(a)(1). But Plaintiff's identification of these statutes also suffer from the same problem. The statutes do not set forth a discrete action that Plaintiff asserts the FDA must take. With respect to section 355-1(a)(1), Plaintiff asserts that this statute "charges the FDA with 'ensur[ing] that the benefits of [a drug submitted for FDA approval] outweigh the risks of the drug.'" (Doc. No. 8, FAC ¶ 123.) Here, Plaintiff only identifies an object to be achieved by the statute. Plaintiff fails to identify a specific action required under this statute that he alleges the FDA has failed to take. Sections 352(f) and 352(j) set forth standards for determining when a drug has been misbranded.[7] But the only labeling action referring to in the FAC and Plaintiff's petition is Plaintiff's request for the FDA to "require labeling of mortality hazards on the Hypnotics." (Doc. No. 8, FAC ¶ 13.) Neither section 352(f) and nor section 352(j) relate to the labeling of morality hazards.

In sum, Plaintiff has failed to identify a discrete act that that the FDA was legally

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[7] Specifically, 21 U.S.C. § 352(f) provides that a drug is misbranded "[u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . ." 21 U.S.C. § 352(j) provides that a drug is misbranded "[i]f it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

required to take under these additional statutes.[8] Therefore, Plaintiff's identification of these additional statutes fail to support his section 706(1) claims. See Hells Canyon, 593 F.3d at 933 ("Because plaintiffs have not identified a 'discrete agency action that [the agency] is required to take,' they have failed to state a claim under § 706(1).").

v. Conclusion

In sum, Plaintiff has failed to adequately state a claim for agency action unlawfully withheld or unreasonably delayed under 5 U.S.C. § 706(1). Accordingly, the Court dismisses Plaintiff's claims for agency action unlawfully withheld and agency action unreasonably delayed.

B. Plaintiff's Claim for Agency Action that is Arbitrary or Capricious, an Abuse of Discretion, or otherwise Not in Accordance with the Law

In the FAC, Plaintiff alleges a cause of action for agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. (Doc. No. 8, FAC ¶¶ 130-31.) Defendants argue that this claim should be dismissed. (Doc. No. 11-1 at 24-25.)

5 U.S.C. § 706(2) provides that a reviewing court must set aside agency action that "is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." In the FAC, Plaintiff identifies as the challenged agency actions, the FDA's tentative response to his petition and the FDA's alleged failure to act within a reasonable time. But as explained with respect to the prior claims, the FDA's tentative response complied with 21 C.F.R. § 10.30(e)(2), and Plaintiff has failed to adequately allege that the FDA has unreasonably delayed ruling on his petition. Thus, Plaintiff has failed to adequately state a claim for agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. Accordingly, the Court dismisses Plaintiff's claim for agency action that is arbitrary, capricious, an abuse of discretion or otherwise not in

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[8] Indeed, in his opposition, Plaintiff fails to even address Defendants' contention that Plaintiff has failed to identify a statutory duty to take action based on these additional statutes. (See generally Doc. No. 13.)

accordance with the law.

Conclusion

For the reasons above, the Court grants Defendants' motion to dismiss Plaintiff's first amended complaint for failure to state a claim.[9] The Court dismisses Plaintiff's first amended complaint without leave to amend.[10] The Clerk is directed to close the case.

IT IS SO ORDERED.

DATED: February 2, 2017

MARILYN L. HUFF, District Judge
UNITED STATES DISTRICT COURT

[9] In their motion to dismiss, Defendants also argue that the first amended complaint should be dismissed for lack of standing. (Doc. No. 11-1 at 8-18.) Because the Court dismisses the first amended complaint without leave to amend for failure to state a claim, the Court declines to address Defendants' standing argument.

[10] The Court declines to grant Plaintiff leave to amend. The deficiencies in the allegations in Plaintiff's FAC that are identified in this order are the exact same deficiencies that were identified by Defendants in their motion to dismiss the original complaint. (See Doc. No. 6-1.) Plaintiff filed a first amended complaint in response to Defendants' motion to dismiss, but Plaintiff was unable to cure the deficiencies identified in this order. Accordingly, the Court concludes that further amendment would be futile. See Telesaurus, 623 F.3d at 1003 ("'A district court may deny a plaintiff leave to amend . . . if the plaintiff had several opportunities to amend its complaint and repeatedly failed to cure deficiencies."); Carrico v. City & Cty. of San Francisco, 656 F.3d 1002, 1008 (9th Cir. 2011) (Leave to amend "is properly denied . . . if amendment would be futile.").

EXHIBIT C

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

DANIEL KRIPKE, on behalf of himself and the general public,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner, United States Food and Drug Administration; UNITED STATES CENTER FOR DRUG EVALUATION AND RESEARCH; JANET WOODCOCK, in her official capacity as Director, United States Center for Drug Evaluation and Research; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and SYLVIA MATTHEWS BURWELL, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

Case No: 3:16-cv-1214-H-BLM

SERVICE LIST FOR APPEAL

Judge: The Honorable Marilyn L. Huff
Location: Courtroom 15A

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Respectfully Submitted,

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